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Medicare: Prescription Drug Proposals

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ABSTRACT

The Medicare program provides significant health insurance coverage for its 39 million aged and disabled beneficiaries. However, the program fails to offer protection against the costs of most outpatient prescription drugs. On June 29, 1999, President Clinton announced the Administration's Medicare reform plan. A key component of this proposal is the establishment of an optional prescription drug benefit for all beneficiaries. A number of other Medicare prescription drug proposals have been offered. Senator Breaux and Congressman Thomas (co-Chairmen of The National Bipartisan Commission on the Future of Medicare) have outlined a plan which would provide a drug benefit for persons with incomes below 135% of the poverty level.

Several Medicare prescription drug bills have already been introduced in the 106th Congress. This report provides an overview of the President's plan, the Breaux-Thomas proposal, and Medicare prescription drug legislation introduced to date in the 106th Congress. It will be updated as additional bills are introduced. It will also track any legislative action. **This report is a supplement to CRS Report RL30147, *Medicare: Prescription Drug Coverage for Medicare Beneficiaries.***

Medicare: Prescription Drug Proposals

Summary

The Medicare program provides significant health insurance coverage for its 39 million aged and disabled beneficiaries. However, the program fails to offer protection against the costs of most outpatient prescription drugs. Many observers contend that this is a significant coverage gap. The absence of a significant drug benefit is not a new concern. The potential cost of adding prescription drug coverage has been the primary impediment to its implementation.

Recently, the issue has received renewed attention as part of the overall discussion of Medicare reform. The National Bipartisan Commission on the Future of Medicare was charged with making recommendations concerning a number of program issues. The Commission failed to get the necessary votes for a reform proposal. However, the plan designed by Senator Breaux and Congressman Thomas is expected to be introduced as legislation in the near future. The Breaux-Thomas plan includes a drug benefit for persons with incomes below 135% of the poverty level.

On June 29, 1999, President Clinton announced the Administration's Medicare reform plan. A key component of this proposal is the establishment of an optional prescription drug benefit for all beneficiaries. Beneficiaries would pay a monthly premium of $24 a month beginning in 2002 (the program's first year) rising to $44 a month when the program is fully phased-in in 2008. There would be no deductible; the program would pay half of drug costs beginning with the first prescription filled. Beneficiaries would be liable for the remaining 50%. The federal government would pay a maximum of $1,000 per person per year in 2002, rising to $2,500 per person per year in 2008. As of this writing a bill incorporating the President's proposal has not been introduced.

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Introduction

The Medicare program provides significant health insurance coverage for its 39 million aged and disabled beneficiaries. However, the program fails to offer protection against the costs of most outpatient prescription drugs. Many observers contend that this is a significant coverage gap. Even though 65% of beneficiaries have some private or public coverage for these costs, they state that many persons do not have adequate supplemental coverage for drug costs and note that beneficiaries themselves pay for half of their drug costs out-of-pocket.

The absence of a significant drug benefit is not a new concern. However, the potential cost of adding prescription drug coverage has been the primary impediment to its implementation. Recently the issue has received renewed attention as part of the overall discussion of Medicare reform.

The Balanced Budget Act of 1997 (BBA 97) established the National Bipartisan Commission on the Future of Medicare. This Commission was charged with making recommendations concerning a number of specific program issues. The Commission was required to report its recommendations to Congress by March 1, 1999. However, by statute, any recommendations had to have the approval of 11 of the 17 Commission members.

Coverage of prescription drugs was one of the most difficult issues facing the Commission. Senator Breaux (Statutory Chairman) and Congressman Thomas (Administrative Chairman) offered a Medicare reform proposal to the Commission members. This proposal established a new drug benefit for the low income population. On March 16, 1999, the Commission voted 10-7 for the Breaux-Thomas plan. Since the proposal failed to get the necessary 11 votes, no formal report was made to the Congress or the President. However, both Senator Breaux and Congressman Thomas have stated that they intend to introduce legislation patterned on their recommendations.

On June 29, 1999, President Clinton announced the Administration's Medicare reform plan. Further details were issued by the White House on July 2, 1999. A key component of the President's proposal is the establishment of an optional prescription drug benefit for all beneficiaries. The benefit would be phased-in over 6 years. The announcement did not include legislative language. As of this writing, a bill incorporating the President's proposal has not been introduced.

Several bills adding a Medicare prescription drug benefit have already been introduced in the 106th Congress. These include: Medicare Outpatient Prescription Drug Coverage Act of 1999 [H.R. 1109 (Engel et. al.)]; Access to Prescription

Medications in Medicare Act of 1999 [H.R. 1495 (Stark et. al.) and S. 841 (Kennedy et. al.)]; Medicare Chronic Disease Prescription Drug Benefit Act of 1999 [H.R. 1796 (Cardin et. al.)]; Medicare Prescription Drug Benefit Act of 1999 [H.R. 2012 (Deutsch and Wexler)]; Seniors Prescription Insurance Coverage Equity (SPICE) Act of 1999 [H.R. 2782 (Pallone and Roukema) and S. 1480 (Snowe and Wyden)], Healthy Seniors Promotion Act of 1999 [S. 1204 (Graham)] and Medicare Ensuring Prescription Drugs for Seniors Act of 1999 [S. 1535 (Grams)]. One measure, Medicare Beneficiary Prescription Drug Assistance and Stop-Loss Protection Act of 1999 [H.R. 2925 (Bilirakis et. al.)], adds benefits for the Medicare population through the Public Health Service Act. One measure establishes a financing mechanism: Medicare Prescription Drug Coverage Act of 1999 [H.R. 886 (Frank et. al.) and S. 696 (Wellstone)]. Two bills would not modify the Medicare program, but would substantially modify the prices seniors pay for drugs: Prescription Drug Fairness for Seniors Act [H.R. 664 (Allen et. al.) and S. 731 (Kennedy et. al.)] and Making Affordable Prescriptions Available for Seniors Act [H.R. 723 (Kennedy et. al.)].

This report provides an overview of the President's plan, the Breaux-Thomas proposal, and Medicare prescription drug legislation introduced to date in the 106th Congress. It will be updated as additional bills are introduced. It will also track any legislative action. **This report is a supplement to CRS Report RL30147, *Medicare: Prescription Drug Coverage for Medicare Beneficiaries.*** That report provides an overview of prescription drug coverage currently available to beneficiaries, presents information on the utilization of drugs by the target population, and outlines some of the major issues that would need to be considered in the design of a drug benefit.

Current Proposals

To date, a number of specific proposals have been offered for adding prescription drug coverage for the Medicare population.[1] Other proposals address the question of affordability of drugs for the senior population but do not add a new federal benefit.

New Medicare Benefit

Scope of Benefits. Several proposals add a new comprehensive benefit to Medicare. Under the President's plan and the SPICE proposal, any beneficiary who voluntarily enrolled in a new Medicare Part D could obtain coverage. Under a number of the pending bills, protection would be available to anyone who was enrolled in the existing Part B program (which covers the costs of physicians and other medical services).

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[1] This report does not include a discussion of legislation which is limited to one particular category of drugs, for example bills which would eliminate the current 3-year limit on the coverage of immunosuppressive drugs (one of the limited category of outpatient prescription drugs currently covered under the program).

An alternative approach would add benefits for the Medicare population through the Public Health Service Act. Under this plan, catastrophic protection ("federal stop-loss protection") would be available for all Medicare beneficiaries if their expenses exceeded a specified amount. Assistance for the low income would only be available to persons in states which chose to set up state prescription drug assistance programs. [H.R. 2925]. Under the Breaux-Thomas plan, coverage would be targeted toward persons with incomes below 135% of poverty; the benefit for this population would be provided through Medicaid with full federal funding.

Many of the measures would add protection for all outpatient prescription drugs provided they met FDA (Food and Drug Administration) criteria and were medically necessary. One bill (H.R. 1796) would restrict coverage to prescription drugs used to treat specified chronic conditions such as hypertension. Another measure (S. 1204) would limit coverage to preventive outpatient prescription drugs which were the direct result of a beneficiary's participation in a preventive screening program.

A few measures would not establish a definition of covered benefits in law, but rather would link *minimum* covered benefits to a threshold level of benefits. Under the SPICE proposal (H.R. 2782/S. 1480), this threshold would be defined by a newly created SPICE Board and would include at least threshold benefits specified by the National Association of Insurance Commissioners (NAIC). Under H.R. 2925, states would define the scope of coverage under their drug assistance programs for the low-income. Coverage could not be less than that offered under a benchmark program such as Medicaid, coverage available to Blue Cross/Blue Shield enrollees under the Federal Employees Health Benefits program (FEHBP), coverage available to state employees, or coverage available to enrollees in the state's largest health maintenance organization (HMO).

Beneficiary Cost-Sharing and Premiums. A key consideration in the development of a Medicare drug bill is the amount beneficiaries will be asked to pay both in cost-sharing and premium charges. Under the President's plan there would be no deductible; the program would pay half of the drug costs beginning with the first prescription filled. Beneficiaries would be liable for the remaining 50%. Most of the other proposals would not cover costs until the beneficiary had satisfied a calendar year deductible (e.g., $200). However, many of these plans would cover 80% of the costs once the deductible had been met. S. 1535 would establish a *monthly* deductible after which 75% of the recognized costs would be paid.

Most proposals would limit the federal exposure. Several measures would place an absolute cap on federal expenditures per person per year. For example, under the President's plan, the federal government would pay 50% of the first $2,000 in drug costs for a maximum federal payment of $1,000. When the plan is fully phased-in, the plan would pay the first 50% of the first $5,000 in expenses for a maximum contribution of $2,500. Under H.R. 2012, no coverage would be provided for costs exceeding $5,200. An alternative approach (H.R. 1495/S. 841) would cover 80% of the costs up to $1,700, provide no coverage of costs between $1,700 and $3,000, and offer full coverage for costs over $3,000.

The federal stop-loss program established under H.R. 2925 would not cover any costs until the beneficiary (who had qualified prescription drug coverage) had incurred

out-of-pocket expenditures exceeding a specified amount ($1,500 in 2000); at that point no further beneficiary cost-sharing would be required.

Cost sharing charges are in addition to any premiums that may be required. Under the President's plan, a separate premium, equal to 50% of program costs, would be established for coverage under the new optional Part D. The Administration estimates that the premium would initially be $24 per month, rising to an estimated $44 when the plan is fully phased-in.

Many of the other bills include prescription drugs as a new Part B benefit. They are by definition providing for an increase in the Part B premium (currently $45.50 per month). By law, beneficiary premiums currently cover 25% of program costs (with federal general revenues covering the remaining 75%). Certain low income beneficiaries can have these Part B premium costs paid for by the federal/state Medicaid program. These persons are known as either: (1) Qualified Medicare Beneficiaries (QMBs) — persons with incomes below 100% of poverty; or (2) Specified Low Income Medicare Beneficiaries (SLIMBs) — persons with incomes below 120% of poverty. In certain cases, persons below 135% of poverty can qualify for payment of their Part B premiums.

The SPICE proposal (H.R. 2782/S. 1480) would provide financial assistance, for persons obtaining drug coverage through a Medicare+Choice plan, a Medicare supplemental policy, or a group health plan. Federal assistance would equal at least 25% of the drug portion of the premium cost; any remaining premium, if any, would be paid by the beneficiary. The specified levels of assistance would be reduced if there were insufficient funds available in the newly established trust fund.

Administration. A major issue in the design of a prescription drug benefit is how the program would be administered. Some would propose using the existing Medicare structure with some changes to permit more private sector involvement in the processing of claims (H.R. 1109, S. 1535). Most proposals recommend the use of private entities, selected on a competitive basis, to administer the program. For example, H.R. 1495/S. 841, H.R. 1796, H.R. 2012, and S. 1204 would award competitively-bid contracts to provide benefits in a geographic area; eligible entities would include pharmaceutical benefit management companies, wholesale and retail pharmacist delivery systems, insurers, other entities, or any combination of these. The President's plan also proposes using similar entities to administer the plan.

Payments for Drugs/Cost Controls. An issue closely linked to program administration is how payments for drugs would be determined. The industry has registered its strong opposition to federal determination of prices — what they label as federal price controls.

Many of the proposals would let the administering entities set up the payment rules that would apply in a geographic area. They would also specifically permit the use of cost control mechanisms, including formularies.[2] Alternatively, two bills (H.R.

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[2] Formularies are lists of drugs which are preferred for use by a health plan.

1109, S. 1535) would set up specific federal payment rules; they would also prohibit the use of formularies.

Protection for Low-Income. Many of the proposals would provide special protections for the low income. The President's plan would ensure that beneficiaries with incomes below 135% of poverty would not pay for premiums or cost-sharing charges. Persons with incomes between 135% and 150% of poverty would receive some assistance with these costs. The Breaux-Thomas plan would provide 100% federal funding for the costs associated with providing coverage to persons below 135% of poverty (not otherwise eligible for Medicaid); the benefit would be administered through Medicaid. H.R. 1495/S. 841 and H.R. 1796 would provide that persons meeting the SLIMB criteria (and not otherwise eligible for Medicaid) would receive comprehensive wrap-around coverage through Medicaid, including assistance with cost-sharing and premiums.

The SPICE proposal (H.R. 2782/ S. 1480) would provide enhanced financial assistance in meeting drug coverage premium costs for persons below 175% of poverty; persons below 150% of poverty would receive 100% of such costs.

Under H.R. 2925, the state drug assistance programs would be limited to persons whose income fell below a level set by the state between 120% and 200% of poverty. No cost-sharing could be imposed on persons whose income was below 120% of poverty.

Financing Mechanism. The President's plan specifies that beneficiaries would pay monthly premiums equal to 50% of the program's cost for the new optional benefit. The President's plan includes a number of modernization proposals for the Medicare program as a whole; the savings from these changes would finance a significant portion of the benefit. In addition, a portion of the projected budget surplus in the U.S. Treasury (i.e., general revenues) would finance the remainder of the new benefit costs.

The SPICE proposal (H.R. 2782/ S. 1480) would be financed through a combination of increases in tobacco taxes and amounts from the federal budget surplus. The bill specifically provides that financial assistance under SPICE could not exceed the amount of money available.

Most of the other proposals would add a new Part B benefit. By definition a portion of the costs would be financed through an increase in the Part B premium (currently $45.50 per month); the remaining costs would be financed from general revenues. Most of the pending bills do not contain specific financing proposals for the remainder of the costs. One measure (H.R. 886/S. 696) calls for the use of federal estate tax revenues to finance a new benefit.

Bills Directed Toward Amounts Seniors Pay for Drugs

Several measures would not add a new Medicare benefit but would limit the prices seniors pay for prescription drugs. One measure (H.R. 664 /S. 731 would provide for substantial reductions in these prices. Another measure (H.R. 723) would

establish a pharmacy assistance program to help elderly low income persons, with no other insurance coverage, to pay for drugs.

Summary of Pending Legislation and Proposals to Establish a New Benefit

The following is a summary of the key features of the President's plan and the Breaux-Thomas proposal. It should be noted that both of these are part of larger Medicare reform proposals; however, only the drug provisions are discussed. This section also summarizes bills introduced in the 106th Congress which would add a new prescription drug benefit. The bills are summarized in the order they have been introduced in the House. Senate bills with no companion House measure are at the end.

The following major features are described for each plan: general approach, persons covered, scope of drug benefits, administration of benefits, reimbursement, beneficiary cost-sharing and premium charges, beneficiary protections, cost control mechanisms/formularies, relationship to group health plans, relationship to Medigap, relationship to Medicaid/assistance for low-income, and financing.

President's Proposal

Note: This summary is based on the detailed description of the President's plan issued by the White House on July 2, 1999.[3]

General Approach. The President's plan is a comprehensive Medicare reform proposal. A major component of the plan is the establishment of a new optional Medicare prescription drug benefit under a newly established Part D. The plan would pay for 50% of beneficiaries drug costs, beginning with the first prescription filled, up to a maximum program payment of $1,000 in the first year (2002) and $2,500 in 2008 when the program is fully phased in.

Persons Covered. Coverage would be extended to all persons, otherwise eligible for Medicare, who enroll in Part D. Persons would only have one chance to enroll. For current beneficiaries, there would be an open enrollment period for the first year the program is in effect (2002). For other persons, the enrollment opportunity would generally occur when an individual first becomes eligible for Medicare. There would be two exceptions. Beneficiaries who are covered by their employer while still working (or by an employer of a working spouse) would have a one-time enrollment opportunity after retirement (or after retirement or death of the working spouse). Beneficiaries covered under a retiree health plan would have a one-time enrollment opportunity if the former employer drops retiree drug coverage.

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[3] For a discussion of the entire proposal see: *Medicare: The President's Reform Proposal*. CRS Report RL30279 by Jennifer O'Sullivan, Madeleine Smith and Sibyl Tilson.

Scope of Benefits. In general, all therapeutic classes of drugs would be covered. In addition, beneficiaries would be guaranteed access to off-formulary drugs when medically necessary and have basic appeal rights when coverage is denied. The exceptions would be for classes of drugs currently excluded under Medicaid except that smoking cessation drugs excluded under Medicaid would be covered under Part D. Drugs currently covered under Medicare would continue to be covered under the Part B program.

Administration of Benefits. The Secretary would contract with private entities who would competitively bid to administer the new drug benefit in a geographic region; only one contract would be awarded in each region. Entities that could compete for the contract include pharmacy benefit managers (PBMs), retail drug chains, health plans or insurers, states (through mechanisms established for Medicaid) or multiple entities in collaboration (such as alliances of pharmacies) provided the collaboration is not anti-competitive. The entity administering a benefit for an area would negotiate prices, process claims, and implement drug utilization review programs. All PBMs or similar entities would be required to meet access and quality standards established by the Secretary.

Benefit managers would be required to enter into contracts with pharmacies that met a set of qualifications, including having necessary information systems to process electronic point-of-sale transactions and create utilization records. Negotiated dispensing fees would have to be high enough to assure participation by most pharmacies.

The government would bear most of the risk for cost and utilization of services under the benefit. The benefit manager would be paid a fee for managing the benefit, and would have some contractual incentives to control costs and utilization.

Enrollees in managed care plans would receive their benefit through the Medicare+Choice plans; for the first time these plans would be paid directly for providing drug coverage.

Reimbursement. Medicare would not set prices for drugs. Prices would be determined through negotiations between the benefit managers for an area and drug manufacturers. It is expected that this process would result in discounts. The proposal would require that beneficiaries would continue to have access to prices established by the benefit manager even after they had exceeded the cap.

Beneficiary Cost-Sharing and Premiums. There is no deductible. The program would pay half of the drug costs beginning with the first prescription filled. Beneficiaries would be liable for the remaining 50%. The program would be phased-in over the 2002-2008 period. In 2002 and 2003, the federal government would pay up to a maximum of $1,000 per person per year (out of the first $2,000 in total spending). In 2004 and 2005, the government would pay up to $1,500 (out of the first $3,000 in total spending). In 2006 and 2007, it would pay up to $2,000 (out of the first $4,000 in total spending). In 2008, it would pay up to $2,500 (out of the first $5,000 in total spending). Beginning in 2009, the limit would be increased by the increase in the consumer price index. The Administration estimates that 90% of beneficiaries would not reach the cap when the program was fully implemented.

Beneficiaries would pay a premium equal to 50% of program costs; the remaining 50% would be paid by the federal government. The Administration estimates that the premium for 2002 would be $24 per month, rising to $44 per month in 2008. CBO (Congressional Budget Office), which has estimated a higher overall cost for the drug benefit, estimates that the monthly premium would be $25.20 per month in 2002, rising to $52.90 per month in 2008. Premiums would be collected in the same way as Part B premiums; for most persons this is a deduction from monthly social security checks.

Beneficiary Protections. All benefit managers would be required to meet access and quality standards established by the Secretary. These standards would include: (1) inclusion of strategies to encourage appropriate use of medications; (2) use of a medical panel, free of conflicts of interest, with outside experts in creating the formulary; (3) use of objective criteria for the formulary; (4) open and fair dealing with drug and biologic companies; (5) publication of criteria for any cost containment measure that could affect patient care; (6) submission of data on costs and utilization on a regular basis; (7) compliance with standards for capacity and pharmacy availability; and (8) compliance with contract requirements and consumer protections, including grievance and appeals procedures.

Cost Control Mechanisms/Formularies. Benefit managers could use various cost containment tools in administering the program, subject to limitations and guidelines set in the contract. They would be permitted to use formularies. However, beneficiaries would be guaranteed access to off-formulary drugs when medically necessary and would have appeal rights when coverage was denied. Private benefit managers would also be authorized to create appropriate incentives for generic substitution.

Relationship to Group Health Plans. Employers would receive a partial drug premium subsidy if their retiree health coverage for drugs is at least as good as the Part D benefit. The subsidy would equal 67% of the amount that would otherwise be provided to the benefit manager for Medicare Part D enrollees. HCFA (Health Care Financing Administration) would make these premium subsidy payments to the health plan or benefit manager used by the employer.

Relationship to Medigap. Medigap policies would be revised to conform to the revised program structure.

Relationship to Medicaid/Assistance for Low-Income. The proposal would make available Part D protection for all beneficiaries, including the low-income. Medicare would therefore pick up some costs currently paid by Medicaid. Under the proposal, Medicaid would pay the Part D drug premiums and cost sharing charges for beneficiaries up to 100% of poverty, using the current federal/state matching rate. Beneficiaries with incomes between 100% and 135% of poverty would have their Part D cost sharing and premium charges paid 100% by the federal government. Persons with incomes between 135% and 150% of poverty would pay a partial sliding scale premium based on income; full federal funding would be provided for the remaining cost sharing.

Financing Mechanism. The Administration estimates federal costs at $29 billion over 5 years (2000-2004) and $118 billion over 10 years (2000-2009). Over 60% of the costs would be financed by savings achieved through efficiencies and economies included under the larger reform plan. A portion of the projected budget surplus ($45.5 billion over 10 years) would finance the remainder of the new benefit costs. CBO estimated the cost of the drug provision at $168 billion over 10 years.

Breaux-Thomas Plan

Note: This summary is based on the proposal presented to the Medicare Commission, March 16, 1999. (Phrases in quotes are from this document.) Since the proposal has not been presented in bill form, some of the specifics are not yet available.

General Approach. The Breaux-Thomas plan is a comprehensive Medicare reform proposal. It includes a premium support plan under which beneficiaries could choose from competing private health plans to obtain their health services; they could also remain in the traditional fee-for-service program. Private health plans and the government run fee-for-service program would be required to offer high option plans which included prescription drug benefits. The proposal would immediately provide federal coverage through Medicaid for prescription drug costs for persons below 135% of poverty.

Persons Covered. Prescription drug coverage would be immediately extended to all persons below 135% of poverty. When the premium support plan was implemented for the entire Medicare population, coverage for low income persons could be provided through high option plans. Other Medicare beneficiaries could also obtain drug coverage through high option plans (though they would be responsible for most, if not all, of the costs of such coverage).

Scope of Benefits. The low income drug benefit would be "comprehensive."

Under the premium support system for the entire Medicare population, all private plans would be required to offer a high option that included at least the standard benefits package (essentially current Medicare benefits) plus coverage for prescription drugs. The minimum drug benefit for high option plans "would be based on an actuarial valuation, with standards and examples set by the [Medicare] Board." The government-run fee-for-service plan would be required to offer high option plans that covered prescription drugs.

Administration of Benefit. The new low-income assistance program for drugs would be administered through the Medicaid program.

A Medicare Board would be established to oversee the new premium support system. All plans (private plans and the government run fee-for-service plan) would compete in the premium support system; all plans would have Board-approved benefit designs and premiums. "The Board would ensure that the benefits provided under all plans are self-funded and self-sustaining, determining whether plan premium

submissions meet strict tests for actuarial soundness, assessing the adequacy of reserves, and monitoring their performance capacity."

The government plan would be self-funded and self-sustaining and meet the same requirements applied to private plans. The government plan would continue to be run through contractors (i.e., carriers and intermediaries); contractors in one region would be able to bid in other regions. The Board "should have powers to assure that the government-run plan would not distort local markets."

Reimbursement. The Board would negotiate premiums with all health plans and compute payments to plans.

Beneficiary Cost-Sharing and Premiums. There would be no cost-sharing for low-income persons qualifying for the new drug benefit.

Under the premium support plan, beneficiaries would be expected to pay, on average, 12% of the total cost of standard option plans.[4] There would be no beneficiary premium for plans costing 85% or less of the national weighted average premium. On the other hand, beneficiaries would pay all premium costs above the national weighted average premiums for plans costing above this level. Only the costs of the standard benefit package would count toward the computation.

High option plans would be required to separately identify the incremental costs of benefits above the standard package. The government contribution would be calculated without regard to the costs of the additional benefits. (Thus in most cases, beneficiaries would pay the full cost of the additional benefits, including prescription drugs.)

A special provision would apply in areas where only the government-run fee for service plan operated. Beneficiary premiums would be limited to the lower of 12% of the fee-for-service premium or 12% of the national weighted average premium, whichever was lower.

Prescription drug coverage for low-income persons could be provided through high option plans when the premium support system was implemented. Special provisions would apply for the government contribution for persons below 135% of poverty. The government would pay 100% of the premiums of high option plans which were at or below 85% of the national weighted average premium of all high option plans. In areas where all high option plans exceeded this threshold, the percentage would be determined locally to ensure that all low-income beneficiaries had access to high option plans. (Low-income persons would not be prevented from paying a premium and purchasing a higher cost plan.)

Private plans could vary copay and deductible structures for their high option plans. The summary indicates that the financial support for the low income "does not

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[4] Under current law, beneficiary Part B premiums are expected to be 12% of total Medicare Part A and Part B expenditures when BBA 97 is fully implemented.

limit these beneficiaries' choice of plans nor restrict plans' design with regard to cost-sharing or other flexibility authorized by the Board."

Cost-Control Mechanisms/Formularies. Cost containment efforts in the fee-for-service sector would continue. The provisions of BBA 97 would be extended or comparable savings achieved. In any region where the price control structure was not competitive, the government would be allowed to pursue competitive pricing strategies.

The government-run high option and standard plans would be required to be separately funded and self-sustaining. "Government contracts would be based on prices commonly available in the market, without recourse to price controls or rebates."

Relationship to Group Health Plans. Not specified.

Relationship to Medigap. All Medigap plans would be required to offer basic coverage for prescription drugs. One plan would be a prescription drug only plan. The coinsurance could vary by plan.

Relationship to Medicaid/Assistance for Low-Income. The new low-income assistance program would be administered through Medicaid with full federal funding of the drug benefit. In addition, *full* federal funding would be provided for any additional costs for the *basic* QMB/SLIMB programs (i.e., cost sharing and premium charges) which occurred as a result of increased enrollment. States would maintain their current level of effort, but the federal government would pay 100% of the additional costs.

Financing Mechanism. The reform plan would combine the Part A and Part B trust funds. Guaranteed general revenue funding could not exceed 40% of the program's cost without congressional approval. The summary states that the entire plan is estimated to reduce the rate of growth in Medicare spending over time and thus achieve program savings.

The low-income prescription drug component would benefit an estimated 6 million persons. It was estimated that the drug provisions would cost the federal government $31 billion over 10 years (FY2000-FY2009) and the expanded QMB/SLIMB coverage would cost an additional $30 billion over the period.

Medicare Outpatient Prescription Drug Coverage Act of 1999 [H.R. 1109 (Engel et. al.)]

General Approach. The bill creates, beginning in 2001, a new drug benefit under Part B. Program payments would equal 80% of program costs after the beneficiary met a deductible ($200 in 2001). The benefit would be administered in a manner similar, but not identical, to that used for other Part B services.

Persons Covered. Coverage is extended to all persons enrolled in Part B.

Scope of Benefits. Coverage would be extended to outpatient prescription drugs meeting FDA criteria. (Drugs currently covered under Part B would be part of the new benefit and subject to the new payment and cost-sharing rules.) The current 3-year limitation on immunosuppressive drugs would be eliminated.

Administration of Benefits. The Secretary would establish a point-of-sale electronic claims system for use by Part B carriers and participating pharmacies. (A point-of-sale electronic system would allow for the immediate processing of claims, including a determination of whether the deductible has been met.) The Secretary could contract with entities other than Part B carriers for implementation and operation of the system; such entities could include a voluntary association, corporation, partnership, or other non-governmental organization which the Secretary determines to be qualified to conduct such activities. The Secretary could require carriers to subcontract with such entities to implement and operate the electronic claims system. The Secretary would develop a standard claims form (and standard electronic claims format) for drug claims.

The law would establish a participating pharmacy program under which pharmacies authorized under state law to dispense drugs would enter into agreements with the Secretary to: (1) accept "assignment" (i.e., agree not to charge patients more than the coinsurance) once the entity is notified the individual has met the deductible; (2) agree not to refuse to dispense covered drugs and not to charge beneficiaries more than charged to the general public; (3) keep patient records, (4) submit information necessary to administer the benefit; and (5) consistent with state law, offer to counsel or to provide information to beneficiaries on the appropriate use of a drug, whether there are potential interactions with other drugs dispensed to the beneficiary, and advise the beneficiary on the availability of therapeutically equivalent drugs.

A new 11-member Prescription Drug Payment Review Commission would be established; it would consist of experts in the fields of health care economics, medicine, pharmacology, pharmacy, and prescription drug reimbursement as well as at least one beneficiary. The Commission would submit an annual report to Congress concerning methods of determining payments for covered outpatient drugs. Beginning in 2002, the report would include information on changes in prices and utilization. The Secretary would also be required to submit an annual report on these issues.

Reimbursement. Payments would equal 80% of the lesser of the actual charge or the payment limit. There would be two payment limits. One category is for multiple source drugs without restrictive prescriptions. Multiple source drugs are those for which there are two or more products rated therapeutically equivalent by the FDA; they must also be pharmaceutically equivalent and bioequivalent. The second category is for non-multiple source drugs and multiple source drugs with a restrictive prescription. A drug has a restrictive prescription if the physician indicates in handwriting (with an appropriate phrase such as "brand medically necessary") that the particular drug must be dispensed. In the case of a telephone prescription, the physician must follow-up with written confirmation within 30 days.

Payment limits for both categories would be established for 6-month payment calculation periods beginning January and July. The payment limit for a non-multiple source drug or drug with a restrictive prescription would be equal to the lessor of: (1)

the 90th percentile of actual charges (computed on statewide, carrier-wide or other geographic basis) based on charges from the second preceding payment calculation period, adjusted to reflect the number of dosage units; or (2) the average wholesale price (AWP) times the number of dosage units, plus an administrative allowance. The payment limit for a multiple source drug without a restrictive prescription would be the sum of: (1) the unweighted median of AWPs times the number of dosage units; and (2) the administrative allowance. In 2001, the administrative allowance would be $5.00 for drugs dispensed by a participating pharmacy and $3.00 for drugs dispensed by other pharmacies. These amounts would be increased in future years by the increase in the implicit price deflator for the gross national product. The Secretary could reduce the allowance for mail service pharmacies.

Beneficiary Cost Sharing and Premiums. The deductible would be $200 in 2001 increased in future years by the percentage increase in the Part B premium. Coinsurance would equal 20% of the payment limit. (The deductible would not apply to immunosuppressive drugs used during the first year following a covered organ transplant.)

Civil monetary penalties would apply if charges by participating or nonparticipating pharmacies to beneficiaries exceed charges to the general public.

Beneficiary Protections. The Secretary would be required to establish a program to identify (and educate physicians and pharmacists concerning): (1) instances or patterns of unnecessary or inappropriate prescribing or dispensing practices for covered drugs; (2) instances or patterns of substandard care for such drugs; and (3) potential adverse reactions. The Secretary would be required to establish prescribing standards for each covered drug based on acceptable medical practice.

Cost Control Mechanisms/Formularies. The Secretary would be prohibited from establishing a formulary to exclude from coverage: (1) any specific drug or class of drug; or (2) any specific use of a drug unless the exclusion is based on a finding that the use is not safe and effective.

The Secretary would be required to develop, update annually, and distribute an information guide for physicians concerning comparative AWPS of at least 500 of the most commonly prescribed covered outpatient drugs.

Payments would generally be limited to a 30-day supply, although the Secretary could authorize up to 90 days (or beyond in unusual cases.)

Relationship to Group Health Plans. No provision.

Relationship to Medigap. No provision

Relationship to Medicaid/Assistance for Low-Income. No provision.

Financing Mechanism. No provision.

Access to Prescription Medications in Medicare Act of 1999 [H.R. 1495 (Stark et. al.) and S. 841 (Kennedy et. al.)]

General Approach. The bill creates a new outpatient prescription drug benefit under Part B beginning July 1, 2000. The benefit has two parts — a basic benefit which covers costs up to $1,700 annually (subject to a deductible and coinsurance) and a "stop loss" benefit under which the program would pay 100% of costs over $3,000 annually. There would be no out-of-pocket costs once the beneficiary reached $3,000 in total drug spending in a year. The benefit would be administered by private entities under contract with Health and Human Services (HHS).

Persons Covered. Coverage would be extended to all persons enrolled under Part B.

Scope of Benefits. Coverage would be extended to outpatient prescription drugs meeting FDA criteria. (Drugs currently covered under Medicare Part B would continue to be covered under the basic Part B program.) The current 3-year limitation on immunosuppressive drugs would be eliminated.

Administration of Benefits. The Secretary would establish procedures for entering into competitively bid contracts with eligible entities to provide drugs in a geographic area. Eligible entities are defined as pharmaceutical benefit management companies, wholesale and retail pharmacist delivery systems, insurers, other entities, or any combination of these. Bids would include the amount of proposed copayment. Contracts could be awarded on a capitation or other basis. At least two contracts would be awarded per area unless only one entity met requirements. Contracts would be for 2-5 years.

The Secretary would assure that the entity: (1) complies with access requirements, (2) complies with formulary requirements (if it employs one);[5] and (3) makes available the full scope of benefits. The Secretary could not enter a contract unless the Secretary determines that the average cost (excluding cost-sharing) for all drugs provided under the contract is comparable to the average cost charged (exclusive of cost-sharing) by large private sector purchasers.

The Secretary would establish a process for eligible beneficiaries to make an election to enroll with any eligible entity that has been awarded a contract (similar to the Medicare+Choice enrollment process). The Secretary would establish procedures: (1) for enrollment of beneficiaries that fail to make an election; (2) for provision of covered outpatient drugs to individuals in areas not covered by contracts, and (3) to ensure that residents residing in different regions during the year are provided benefits throughout the year.

Reimbursement. The Secretary would establish procedures for making payments to an eligible entity. These entities would determine pricing policies.

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[5] Formularies are lists of drugs which are preferred for use by a health plan.

Beneficiary Cost Sharing and Premiums. The deductible would be $200. Coinsurance could not exceed 20% of cost (as stated in contract). No coverage would be provided for costs between $1,700 and $3,000; however, the beneficiary could continue to purchase drugs at contract price. Full coverage would be provided for costs over $3,000. Basic and stop loss benefit amounts would be annually adjusted based on changes in per capita prescription costs for beneficiaries.

Beneficiary Protections. The Secretary could not award a contract unless the Secretary finds that the entity is in compliance with terms and conditions specified by the Secretary including those relating to: (1) quality and financial standards; (2) provision of necessary information to the Secretary; (3) establishment of educational program, meeting criteria established by the Secretary, to assure appropriate prescribing, dispensing, and use of covered therapies; (4) procedures to assure proper utilization and to avoid adverse drug reactions; (5) assuring that drugs are accessible and convenient to covered beneficiaries (including offering services 24 hours a day, 7 days a week for emergencies and offering services at a sufficient number of retail pharmacies); (6) compensation of pharmacists for providing counseling to beneficiaries regarding use of drugs; and (7) procedures to review and resolve complaints and denials (that are comparable to those under Medicare+Choice). The entity is required to safeguard the privacy of any individually identifiable information.

Cost Control Mechanisms/Formularies. The entity could employ mechanisms to provide benefits economically including formularies, alternative methods of distribution, generic drug substitution, and using incentives to encourage beneficiaries to select cost effective drugs or less costly means of receiving drugs. If a formulary is used, the entity is to (1) ensure participation of physicians and pharmacists in development; (2) include at least one drug from each therapeutic class; (3) provide for coverage of other non-formulary drugs when recommended by participating providers; and (4) disclose the nature of formulary restrictions. Nothing precludes an entity from requiring higher cost-sharing for non-formulary drugs (except when medically indicated).

Relationship to Group Health Plans. If retirees receive at least equivalent benefits under a group health plan, they may continue to receive services through that plan. HHS would provide payment to the plan equal to the payment that would otherwise have been paid on behalf of the beneficiary.

Relationship to Medigap. The Secretary and NAIC would be required to revise the standard Medigap packages to reflect new coverage; an appropriate number of policies would be required to offer complimentary (not duplicative) coverage.

Relationship to Medicaid/Assistance for Low-Income. The income limit for the SLIMB program would be increased to from 120% 135% of poverty thereby extending Part B premium assistance to this group. Beneficiaries with incomes between the level for Medicaid eligibility and 135% of poverty would receive comprehensive wrap around drug coverage through Medicaid.

Financing Mechanism. No provision. However, Senator Kennedy in his introductory remarks suggested looking at a number of options including using a portion of the federal budget surplus, recovering Medicare costs of treating tobacco

related illnesses, increasing the tobacco tax, and using savings achieved from Medicare reform legislation.

Medicare Chronic Disease Prescription Drug Benefit Act of 1999

[H.R. 1796 (Cardin et. al.)]

General Approach. The bill creates, beginning in 2001, a new outpatient chronic disease prescription drug benefit under Part B. The benefit would be administered by private entities under contract with HHS.

Persons Covered. Coverage would be extended to all persons enrolled under Part B.

Scope of Benefits. Coverage would be extended to outpatient prescription drugs, meeting FDA criteria, which are used to treat the following chronic conditions: hypertension, diabetes, congestive or ischemic heart disease, major depression, and rheumatoid arthritis. Coverage would be limited to drugs which have been shown to have a demonstrable effect in treating these conditions. The Secretary would implement a process for the timely identification of such drugs; the Secretary would utilize recommendations made by the Agency for Health Care Policy and Research.

Administration of Benefits. The Secretary would establish procedures for entering into competitively bid contracts with eligible entities to provide drugs in a geographic area. Eligible entities are defined as pharmaceutical benefit management companies, wholesale and retail pharmacist delivery systems, insurers, other entities, or any combination of these. Bids would include the amount of proposed copayment. Contracts could be awarded on shared risk, capitation, or performance basis. Contracts would be for 2-5 years.

The Secretary would assure that the entity: (1) complies with access requirements; and (2) complies with formulary requirements (if it employs one). The entity would have to make available to each beneficiary at least one drug in each therapeutic class from those approved by the Secretary; it would also have to make available at least one generic equivalent for each drug if available. Further, the entity would also have to make available alternative drugs if a physician certifies that such alternatives are medically necessary.

The Secretary would establish a process for eligible beneficiaries to make an election to enroll with any eligible entity that has been awarded a contract (similar to the Medicare+Choice enrollment process). The Secretary would establish procedures: (1) for enrollment of beneficiaries that fail to make an election; (2) for provision of covered outpatient drugs to individuals in areas not covered by contracts; and (3) to ensure that residents residing in different regions during the year are provided benefits throughout the year.

Reimbursement. The Secretary would establish procedures for making payments to an eligible entity. These entities would determine pricing policies.

Beneficiary Cost-Sharing and Premiums. The deductible would be $250. Coinsurance could not exceed 20% of cost (as stated in contract). No copayments would be permitted for generic drugs.

Beneficiary Protections. The Secretary could not award a contract unless the Secretary finds that the entity is in compliance with terms and conditions specified by the Secretary including those relating to: (1) quality and financial standards; (2) provision of necessary information to the Secretary; (3) establishment of educational program, meeting criteria established by the Secretary, to assure appropriate prescribing, dispensing, and use of covered therapies; (4) procedures to assure proper utilization and to avoid adverse drug reactions; (5) assuring that drugs are accessible and convenient to covered beneficiaries (including offering services 24 hours a day, 7 days a week for emergencies and offering services at a sufficient number of retail pharmacies); (6) compensation of pharmacists for providing counseling to beneficiaries regarding use of drugs; and (7) procedures to review and resolve complaints and denials (that are comparable to those under Medicare+Choice. The entity is required to safeguard the privacy of any individually identifiable information.

Cost Control Mechanisms/Formularies. The entity could employ mechanisms to provide benefits economically including formularies, alternative methods of distribution, generic drug substitution, and using incentives to encourage beneficiaries to select less costly means of receiving drugs. If a formulary is used, the entity is to (1) ensure participation of physicians and pharmacists in development; (2) include at least one drug from each therapeutic class and provide at least one generic equivalent where available; (3) provide for coverage of other non-formulary drugs when recommended by participating providers; and (4) disclose the nature of formulary restrictions. Nothing precludes an entity from requiring higher cost-sharing for non-formulary drugs (except when medically indicated).

Relationship to Group Health Plans. No provision

Relationship to Medigap. No provision

Relationship to Medicaid/Assistance for Low-Income. Persons meeting SLIMB criteria would have their cost sharing charges paid by Medicaid.

Persons could receive benefits through an existing state non-Medicaid prescription drug program. The state program could not impose cost-sharing in excess of that specified under this bill. HHS would make payments to the state program; these could not exceed what would be paid in the absence of the state program.

Financing Mechanism. No provision.

Medicare Prescription Drug Benefit Act of 1999 [H.R. 2012 (Deutsch and Wexler)]

This bill is virtually identical to H.R. 1495/S. 841 except for the cost sharing provisions. H.R. 2012 specifies that the deductible would be $200 in 2000 increased in future years by the percentage increase in the per capita cost of drugs under the

program. Coinsurance could not exceed 20% of the cost (as stated in the contract). Coverage would be provided for costs up to $5,200 (adjusted in future years by changes in per capita costs). No coverage would be provided for costs over that amount; however, the beneficiary could continue to purchase drugs at the contract price.

The other main change from H.R. 1495/S. 841 is that H.R. 2012 does not include a requirement that an eligible entity administering the benefit be required to compensate pharmacists for providing counseling to beneficiaries on the use of drugs.

Seniors Prescription Insurance Coverage Equity (SPICE) Act of 1999 [H.R. 2782 (Pallone and Roukema) and S. 1480 (Snowe and Wyden)]

General Approach. The SPICE bill creates a new voluntary prescription drug benefit under a new Part D. Beneficiaries would be able to obtain SPICE coverage through enrollment in a Medicare+Choice plan, enrollment in a SPICE Medicare supplemental policy, or coverage under a group health plan. The policies would be required to meet a minimum threshold level of benefits. All persons who enroll in SPICE would receive financial assistance. At a minimum enrollees would receive assistance equal to 25% of the premium cost. Low-income persons below 150% of poverty would receive enhanced premium support, with those under 100% of poverty receiving 100% premium support. However, the specified levels of financial assistance would be reduced if there were insufficient funds available in the SPICE trust fund.

Persons Covered. Coverage would be extended to all persons, entitled to both Parts A and B, who voluntarily enroll in the program. Penalties would be established for delayed enrollment.

Scope of Benefits. "SPICE prescription drug coverage" would be coverage the SPICE Board determined met certain conditions. The benefits would be: (1) limited to outpatient prescription drugs, (2) include at least specified threshold benefits as developed by NAIC; and (3) exclude coverage for drugs already covered by Medicare. Further, the benefits must be accessible and convenient, and access must be provided on a timely basis to new outpatient prescription drugs as they become available. Plans could not contain language excluding coverage relating to a pre-existing condition.

The SPICE Board would request NAIC to revise model standards for Medigap policies for the purpose of defining "outpatient prescription drugs" and specifying a threshold level of SPICE drug coverage. The definition of outpatient drugs would take into account the definition of covered drugs under Medicaid. The threshold level would take into account the level of such coverage (including deductibles and cost-sharing requirements) offered under the FEHBP and under other large group health plans. The threshold level could permit (if determined appropriate) coverage of drugs (except those used for promotion of smoking cessation) that are restricted or excluded under Medicaid.

All "SPICE prescription drug coverage" must include at least the specified threshold level of benefits and may include coverage above the threshold level.

Administration of Benefits. The program would be administered by a 7-member SPICE Board which would be broadly representative of consumers, private plan insurers (including those that offer fee-for-service and managed care plans), HCFA, and state insurance commissioners. The Board, which would run a SPICE Office within HHS, would be separate from HCFA. The SPICE Board would administer the SPICE benefit. It would be required to conduct a series of ongoing studies relating to the benefit.

The SPICE Board would broadly disseminate information to beneficiaries on the SPICE benefit program, including information on penalties for delayed enrollment. The SPICE Board would establish the procedures through which a beneficiary could elect to enroll, disenroll, and change enrollment in a SPICE medicare supplement policy or a Medicare+Choice plan that includes SPICE drug coverage. The Board would: (1) use rules similar to those established for Medicare+Choice enrollment (including annual open enrollment periods and guaranteed issue during any enrollment period); (2) permit special enrollment periods for persons enrolled in a Medicare+Choice plan or group health plan with SPICE coverage who lose such coverage or experience a significant adverse income level change (as defined by the Board) which changes the level of financial assistance available; and (3) provide for coordination with HHS.

The SPICE Board would establish procedures for reducing the amount of financial assistance provided if an eligible individual fails to obtain or maintain SPICE coverage. The procedures could be similar to the Part B delayed enrollment penalty provisions that apply under current law. Late enrollment penalties would not apply to a Medicare+Choice or group health plan enrollee who lost SPICE coverage because the plan dropped such coverage or terminated; this exception would be contingent upon the beneficiary seeking to obtain SPICE coverage at the next available opportunity.

The SPICE Board would also establish procedures for persons desiring enhanced financial assistance to apply voluntarily for an income determination by the Board.

Financial assistance would be paid by the SPICE Board to the appropriate SPICE supplement policy, Medicare+Choice plan, or group health plan. The payment would not be made unless an application had been submitted to the Board (in accordance with procedures established by it) and approved by the Board. Further, a SPICE supplement policy or Medicare+Choice plan would have to meet enrollment requirements established by the Board. The Board could disapprove or revoke the approval of an application of such supplement policy or Medicare+Choice plan if the Board finds that the entity offering the coverage is purposefully engaged in activities designed to result in favorable selection of beneficiaries obtaining coverage through the plan.

Financial assistance under SPICE could not exceed the amount of money available in the SPICE trust fund. The Board's annual report would include a report on the financial status of the SPICE trust fund. If necessary (based on such status)

it would also include a statement on how any required reduction in financial assistance in the subsequent year would be made. (See **Cost-Sharing** below.) The report could also include recommendations concerning expanding the amount of financial assistance, to the extent funds were available.

Reimbursement. The SPICE Board would provide the financial assistance for a beneficiary directly to the issuer of the SPICE supplement policy, the Medicare+Choice organization, or the sponsor of the group health plan. Entities receiving assistance would have to provide assurances that they reduced the amount charged the beneficiary by an equivalent amount.

Beneficiary Cost-Sharing and Premiums. All persons with SPICE coverage would receive financial assistance equal to at least 25% of the "applicable cost" of coverage. Persons below 150% of poverty would receive 100% of such cost. The support would be scaled-down from 100% to 25% for those with incomes between 150% and 175% of the poverty line. "Applicable cost" is defined as: (1) the premium for a SPICE supplemental policy; (2) the actuarial value of the portion of the adjusted community rate for the Medicare+Choice plan that is related to providing SPICE coverage; or (3) the actuarial portion of a group health plan premium related to providing SPICE coverage. The financial assistance for persons enrolled in a Medicare+Choice plan cannot exceed that portion of the enrollment premium that is related to drug coverage.

Financial assistance under SPICE could not exceed the amount of money available in the SPICE trust fund. If the SPICE Board determined that the amounts in the trust fund were insufficient for the following year, it would be required to take the following steps. First, it would reduce the minimum financial assistance percentage from 25% to not less than 10%. If this reduction was insufficient, the Board would next reduce the income thresholds specified for the low-income. If these reductions was still not sufficient, the Board would immediately report to Congress and suspend the provision of financial assistance.

The SPICE bill does not specify any cost-sharing that may be required by the plans.

Beneficiary Protections. The SPICE Board would be required to study ways in which drug utilization could be used to provide better overall care for beneficiaries.

Cost-Control Mechanisms/Formularies. An entity offering SPICE coverage would be permitted to use reasonable cost containment methods such as formularies, mail order services, and generic drug substitution, consistent with the requirements of SPICE and applicable law. If a formulary is used: (1) it must be based on the medical needs of beneficiaries; (2) the entity offering coverage must have an appeals process in place that is similar to or better than that available under Medicare+Choice; (3) the procedures do not impose a significant financial burden on beneficiaries or delay the provision of medically necessary drugs; and (4) the entity offering coverage provides at least a 60 day notice of any change in the formulary.

Relationship to Group Health Plans. Group health plans providing SPICE prescription drug coverage would receive financial assistance on behalf of enrolled beneficiaries.

Relationship to Medigap. The definition of standardized Medigap benefit packages would be changed. One package would cover only outpatient prescription drugs. This drug-only package would be consistent with SPICE prescription drug coverage and be offered only through the SPICE Board. The package would permit coverage that exceeded the threshold levels.

No other Medigap policies could include drug coverage except that persons who currently have such policies would be permitted to retain and renew them provided that: (1) they are informed that so long as they keep such a policy they cannot purchase a SPICE medicare supplemental policy; and (2) they are offered a Medigap policy which is comparable to the policy which they currently have (except for prescription drug coverage).

The SPICE Board, in conjunction with the NAIC, would be required to study permitting a Medicare supplement benefit package which included drugs but was not a drugs-only policy. The Board would submit its recommendations to Congress.

Relationship to Medicaid/Assistance for Low-Income. Low-income beneficiaries would receive enhanced financial assistance. (See **Beneficiary Cost-Sharing and Premiums,** above.)

Financing Mechanism. A separate SPICE trust fund would be created. Income to the trust fund would consist of: (1) the amount of the increase in the tobacco taxes (as provided for under the bill), and (2) amounts from the on-budget surplus.

Healthy Seniors Promotion Act of 1999 [S.1204 (Graham)]

General Approach. The bill contains a number of provisions focusing on health promotion and disease prevention among the elderly. It authorizes coverage for several additional preventive benefits under Medicare and adds coverage for preventive outpatient drugs beginning in 2002. The drug benefit would be subject to an annual limit ($750 in 2002). The following discussion summarizes the drug provision of the bill.

Persons Covered. Coverage would be extended to all persons enrolled under Part B.

Scope of Benefits. Covered drugs would be limited to preventive outpatient prescription drugs (not otherwise covered by Medicare) which are the direct result of an individual's participation in: 1) a screening mammography; 2) screening pap smear or screening pelvic exam; 3) prostate cancer screening test; 4) colorectal cancer screening test; 5) diabetes outpatient self-management training service; 6) bone mass measurement; 7) cessation of tobacco use training program; 8) screening for hypertension; 9) counseling for hormone replacement therapy; 10) screening for

glaucoma; and 11) any other preventive service added by the Secretary. Screening services in items 1-6 are covered under current law while those in items 7-10 are new preventive benefits added by the bill. The Secretary is required to ensure that all preventive outpatient prescription drugs that are reasonable and necessary to prevent or slow the deterioration of, and improve or maintain the health of eligible beneficiaries are offered under a contract with an eligible entity.

Administration of Benefits. The Secretary would establish procedures for entering into competitively bid contracts with eligible entities to provide drugs in a geographic area. Eligible entities are defined as pharmaceutical benefit management companies, wholesale and retail pharmacist delivery systems, insurers, or any combination of these. Bids would include the amount of proposed coinsurance. Contracts could be awarded on shared risk, capitation, or performance basis. At least two contracts would be awarded per area unless only one bidding entity meets the criteria. Contracts would be for 2-5 years.

The Secretary would ensure that the entity complies with access requirements and makes available the full scope of benefits.

The Secretary would establish a process for eligible beneficiaries to make an election to enroll with any eligible entity that has been awarded a contract (similar to the Medicare+Choice enrollment process). The Secretary would establish procedures: (1) for enrollment of beneficiaries that fail to make an election; (2) for provision of covered outpatient drugs to individuals in areas not covered by contracts; and (3) to ensure that residents residing in different regions during the year are provided benefits throughout the year.

Reimbursement. The Secretary would establish procedures for making payments to an eligible entity. These entities would determine pricing policies.

Beneficiary Cost-Sharing and Premiums. The deductible would be $50. Coinsurance could not exceed 20% of the cost (as stated in the contract). Each time a prescription was filled, a beneficiary would be liable for a copayment equal to the lesser of the cost of the drug (minus the deductible and coinsurance) or $5.

Program payments would cease after the aggregate amount of preventive outpatient prescription drugs exceeded $750 in a year (based on the cost as stated in the contract); however, beneficiaries could continue to purchase drugs at the contract price. The $750 limit would be increased each year by changes in the per capita cost of prescription drugs for beneficiaries.

Beneficiary Protections. The Secretary could not award a contract unless the Secretary finds that the entity is in compliance with terms and conditions specified by the Secretary including those relating to: (1) quality and financial standards; (2) provision of necessary information to the Secretary; (3) procedures to assure proper utilization and to avoid adverse drug reactions; (4) assuring that drugs are accessible and convenient to covered beneficiaries (including offering services 24 hours a day, 7 days a week for emergencies and offering services at a sufficient number of retail pharmacies); and (5) procedures to review and resolve complaints and denials (that

are comparable to those under Medicare+Choice. The entity is required to safeguard the privacy of any individually identifiable information.

Cost-Control Mechanisms/Formularies. The entity could employ mechanisms to provide benefits economically including formularies, alternative methods of distribution, generic drug substitution, and using incentives to encourage beneficiaries to select less costly means of receiving drugs.

Relationship to Group Health Plans. No provision.

Relationship to Medigap. No provision.

Relationship to Medicaid/Assistance for Low-Income. Medicaid coverage for preventive outpatient prescription drugs would be provided under Medicaid for persons with incomes below 135% of poverty. Full federal funding would be provided for any additional costs. States would be required to maintain their expenditures for any state-funded prescription drug program at least at the FY1999 level.

Financing Mechanism. Fifty percent of any amount received by the federal government from any legislation providing for a global tobacco settlement would be transferred to Part B. This money would be used to enhance the drug benefit consistent with recommendations made in an Institute of Medicine study (which is required under the under the bill).

Medicare Outpatient Prescription Drug Coverage Act of 1999 [S. 1535 (Grams)]

General Approach. The bill creates, beginning in 2001, a new drug benefit under Part B. Program payments would equal 75% of the recognized payment amount after the beneficiary met a *monthly* deductible ($150 in 2001). The deductible would be waived for persons with incomes below 135% of poverty. The benefit would be administered in a manner similar, but not identical, to that used for other Part B services.

Persons Covered. Coverage is extended to all persons enrolled in Part B.

Scope of Benefits. Coverage is extended to outpatient prescription drugs meeting FDA criteria. (Drugs currently covered under Part B would be part of the new benefit and subject to the new payment and cost-sharing rules.) The current 3-year limitation on immunosuppressive drugs would be eliminated.

Administration of Benefits. The Secretary would establish a point-of-sale electronic claims system for use by Part B carriers and participating pharmacies. (A point-of-sale electronic system would allow for the immediate processing of claims, including a determination of whether the deductible has been met.) The Secretary could contract with entities other than Part B carriers for implementation and operation of the system; such entities could include a voluntary association, corporation, partnership, or other non-governmental organization which the Secretary

determines to be qualified to conduct such activities. The Secretary could require carriers to subcontract with such entities to implement and operate the electronic claims system. The Secretary would develop a standard claims form (and standard claims format) for drug claims.

The law would establish a participating pharmacy program under which pharmacies authorized under state law to dispense drugs would enter into agreements with the Secretary to: (1) accept "assignment" (i.e., agree not to charge patients more than the coinsurance) once the entity is notified the individual has met the deductible; (2) agree not to refuse to dispense covered drugs and not to charge beneficiaries more than charged to the general public; (3) keep patient records, (4) submit information necessary to administer the benefit; and (5) consistent with state law, offer to counsel or to provide information to beneficiaries on the appropriate use of a drug, whether there are potential interactions with other drugs dispensed to the beneficiary, and advise the beneficiary on the availability of therapeutically equivalent drugs.

A new 11-member Prescription Drug Payment Review Commission would be established; it would consist of experts in the fields of health care economics, medicine, pharmacology, pharmacy, and prescription drug reimbursement as well as representatives of the prescription drug manufacturing industry and at least one beneficiary. The Commission would submit an annual report to Congress concerning methods of determining payments for covered outpatient drugs. Beginning in 2002, the report would include information on changes in prices and utilization. The Secretary would also be required to submit an annual report on these issues.

Reimbursement. Payments would equal 75% of the *lesser of* the actual charge or the average wholesale price.

Beneficiary Cost Sharing and Premiums. The deductible would be $150 *a month* ($300 for a couple) in 2001 increased in future years by the percentage increase in the Part B premium. Coinsurance would equal 25% of the recognized payment amount.

Civil monetary penalties would apply if charges by participating or nonparticipating pharmacies to beneficiaries exceed charges to the general public.

Beneficiary Protections. Participating pharmacies would be required, consistent with state law, to offer to counsel or provide information to beneficiaries on the appropriate use of a drug and whether there are potential interactions with other drugs dispensed to the beneficiary.

Cost Control Mechanisms/Formularies. The Secretary would be prohibited from establishing a formulary to exclude from coverage: (1) any specific drug or class of drug; or (2) any specific use of a drug unless the exclusion is based on a finding that the use is not safe and effective.

Payments would generally be limited to a 30-day supply, although the Secretary could authorize up to 90 days (or beyond in unusual cases.)

Relationship to Group Health Plans. No provision.

Relationship to Medigap. No provision

Relationship to Medicaid/Assistance for Low-Income. The deductible would not apply to persons below 135% of poverty.

Financing. No provision.

Summary of a Bill to Add a Non-Medicare Benefit for the Medicare Population

Medicare Beneficiary Prescription Drug Assistance and Stop-Loss Protection Act of 1999 [H.R. 2925 (Bilirakis et.al.)]

General Approach. The bill would amend the Public Health Service Act to establish two programs for Medicare beneficiaries—state prescription drug assistance and federal stop-loss drug protection. Under the state drug assistance program, federal matching funds would be provided to states who voluntarily set up prescription drug coverage programs for their low-income Medicare population; coverage would be available for persons not eligible for drug coverage under the state's Medicaid program. The federal stop-loss protection would limit Medicare beneficiaries out-of-pocket liability for drugs; initially the annual limit would be set at $1,500. These two plans are described separately below.

State Drug Assistance Program

Persons Covered. The state drug assistance program would cover low income persons in states that chose to set up a program. Low income persons are defined as persons: (1) eligible for Medicare Part A and/or Part B; (2) not eligible for drug coverage under the state's Medicaid program; (3) whose income falls below the level set by the state which must be between 120% and 200% of poverty; and (4) at the option of the state, has resources below a level set by the state (which could not be lower than $4,000 for an individual, $6,000 for a couple).

Scope of Benefits. The "scope and quality" of drug benefits under the state assistance program would be set by the state but could not be less than that offered under one of the following: (1) the state's Medicaid program; (2) the standard Blue Cross/Blue Shield plan under FEHBP; (3) the coverage available to state employees; (4) coverage available to enrollees in the state's largest HMO (as defined by its commercial non-Medicaid enrollment); or (5) other benchmark coverage that the Secretary determines, upon application by the state, provides comprehensive outpatient drug coverage. The term "scope and quality" means the extent of drugs covered (including any exclusions or limitations and the application of any formulary (including exceptions to the formulary) and provisions to assure access to and quality of covered drugs. The term does not include cost sharing requirements. State programs would be prohibited from imposing any maximum annual lifetime or other durational limits. State programs could not impose any preexisting condition exclusion.

The state drug assistance programs could not include coverage for items currently covered under Medicare, items for which coverage is not available under Medicaid, or drugs used for assisted suicide.

Administration of Benefits. A state would be eligible for assistance if it submitted to the Secretary a plan which included a written document that outlined how the state intended to use the federal funds and the procedures to be used to provide for outreach to low-income beneficiaries. Further, the state would have to provide a certification by the chief executive officer of the state that the state drug assistance program is consistent with the specific requirements of the bill.

A state would be required to provide assurances to the Secretary that: (1) it would collect data, maintain records and furnish reports as specified by the Secretary in order to enable the Secretary to monitor state program administration and compliance and to evaluate and compare state programs; (2) it would afford the Secretary access to records and information for the purposes of review and audit; and (3) it would assess and report to the Secretary annually on state program operation.

The Secretary could not impose conditions in addition to those specified under the bill for state drug assistance programs.

The Secretary would pay each state that submitted a drug assistance plan an amount for each quarter (beginning on or after October 1, 1999) equal to the sum of: (1) the enhanced federal match for expenditures for low-income beneficiaries with family incomes below 150% of poverty; (2) the federal matching rate that applies under the state's Medicaid program for expenditures for other low income beneficiaries covered under the state's program; and (3) the enhanced matching rate for expenditures related to outreach and other administrative activities (except that assistance for administrative expenses cannot exceed 20% of the total federal contribution in the first year or 10% in subsequent years). The enhanced matching rate is defined as the federal matching rate for the state's Medicaid program plus 30% of the percentage point difference between this rate and 100% [for example a state with a 60% federal Medicaid match rate would have an enhanced rate of 72% (60% +0.3 x 40)]. In no case could the federal rate exceed 85%.

Reimbursement. The state would be required to provide low-income assistance to each eligible person who applied for coverage. States would be required to provide the assistance as a premium subsidy for persons enrolled in a Medicare+Choice or group health plan that provides qualified prescription drug coverage. The amount of the subsidy would would equal the portion of the premium attributable to furnishing drug coverage. For other persons, the state could select any method for the provision of, or payment for, qualified coverage, provided it is separate from Medicaid.

Beneficiary Cost-Sharing and Premiums. A state drug assistance program could not impose a premium, enrollment fee, or deductible for drug coverage. No copayments or coinsurance charges could be imposed for persons whose family income was below 120% of poverty. For persons with higher incomes, cost-sharing could not exceed the greater of $5 per prescription unit or 20% coinsurance. In the aggregate, cost-sharing could not exceed an annual limit; the limit would be $1,500

in 2000. This limit would be increased in future years by the percentage increase in per capita expenditures for prescription drugs over the period July 1999 to July of the year prior to the year in question.

Beneficiary Protections. No provision.

Cost/Control Mechanisms/Formularies. The Secretary could not require states to use any particular formulary or pricing structure. States would be prohibited from using the Medicaid rebate system or any other federal rebate system.

Relationship to Group Health Plans. Low-income persons enrolled in group health plans with qualified drug coverage would have a premium subsidy payment made in their behalf.

Relationship to Medigap. Medicare beneficiaries provided low-income assistance would be permitted to drop a Medigap policy which includes drug coverage and be able to purchase another policy offered by the insurer. Beneficiaries who lose low-income prescription drug assistance would be permitted to restore Medigap coverage that included prescription drug coverage. In addition, the Secretary would establish a 6-month open enrollment period when all beneficiaries would be able to obtain a Medigap policy with prescription drug coverage.

Relationship to Medicaid/Assistance for Low-Income. See above.

Financing. No provision.

Federal Stop-Loss Protection

Persons Covered. The federal stop-loss protection program would be available for persons enrolled in Part A and/or B who have qualified Medicare prescription drug coverage. Qualified coverage is defined as drug coverage meeting the following requirements: (1) the deductible cannot exceed $500 in a year; (2) cost-sharing (in the form of copayments, coinsurance, or both) could not exceed 50% of the payment amount for the drug; (3) there is an annual per beneficiary limit of not more than $1,500 on out-of-pocket expenses; and (4) the entity offering the coverage has entered into an agreement with the entity administering stop-loss protection under which it agrees to provide for the information necessary to establish eligibility for program payments. Plans meeting these requirements could be Medicare+Choice plans, Medigap policies, or group health plans.

Scope of Benefits. The federal stop-loss program would pay the costs of providing benefits under a qualified Medicare prescription drug coverage plan once a beneficiary had incurred out-of-pocket expenses exceeding a specified amount. This amount would be $1,500 in 2000. It would be increased in future years by the percentage increase in per capita expenditures for prescription drugs over the period July 1999 to July of the year prior to the year in question.

Administration of Benefits. The Secretary would enter into contracts with one or more carriers or other qualified entities to operate the stop-loss program. The

program would make the stop-loss payments to the entity providing the qualified Medicare prescription drug coverage.

Reimbursement. No provision.

Beneficiary Cost-Sharing and Premiums. No cost sharing would be required once the beneficiary hit the stop-loss coverage threshold.

Beneficiary Protections. No provision.

Cost/Control Mechanisms/Formularies. The Secretary, carrier, or other qualified entity would not be authorized to deny or limit payment under the plan. However, the Secretary, carrier or entity could compute costs taking into account discounts or other rebates related to the provision of drug coverage.

Relationship to Group Health Plans. See above.

Relationship to Medigap. See low-income program, above.

Relationship to Medicaid/Assistance for Low-Income. See low-income program, above.

Financing. No provision.

Financing Measure

Medicare Prescription Drug Coverage Act of 1999 [H.R. 886 (Frank et. al.), S. 696 (Wellstone)]

The bill provides for the transfer of federal estate tax revenues to the Federal Hospital Insurance Trust Fund under Medicare (Part A of the program). It establishes an Outpatient Prescription Drug Account in the Trust Fund to receive such revenues and to pay for outpatient prescription drugs furnished under the program.

Within 180 days of enactment, the Secretary would be required to submit a plan to Congress providing for the full coverage of outpatient prescription drugs for Medicare beneficiaries. The report is to include a determination of whether the estate tax revenues are sufficient to fund this drug benefit.

Measures Directed Toward Amounts Seniors Pay For Drugs

Prescription Drug Fairness for Seniors Act [H.R. 664 (Allen et. al.), S. 731 (Kennedy et. al.)]

The bill would require each participating manufacturer of a covered outpatient drug to make available for purchase by each pharmacy quantities of covered drugs equal to the aggregate amount of the drug sold or distributed by the pharmacy to Medicare beneficiaries. (Covered drugs are those which are covered by Medicaid.) Participating manufacturers are defined as any manufacturer of drugs or biologicals that enters into a contract or agreement with the United States for the sale or distribution of covered outpatient drugs to the United States.

The manufacturers would be required to make the drug available at a price equal to the lower of : (1) the lowest price paid for the drug by *any agency or department of the United States*; or (2) the manufacturer's "best price" for the drug as that term is defined under Medicaid.

The bill directs the Secretary to implement the requirements as expeditiously as practicable and in a manner consistent with the obligations of the United States.

Making Affordable Prescriptions Available for Seniors Act [H.R. 723 (Kennedy et. al.)]

The bill would establish a pharmacy assistance program under the Public Health Service Act. The assistance would be provided in the manner the Secretary determined to be the most cost effective including indemnification, vouchers, coupons, or direct provider reimbursement through the Medicaid claims payment system. No cash payment could be made to an eligible person before presentation of a receipt or other invoice. Persons eligible for the benefit would be persons over age 65 with no other drug coverage whose income did not exceed 175% of poverty. The assistance could not exceed $500 per person per year.

The Secretary could impose an enrollment fee of up to $15 per year. The Secretary would be required to develop copayment requirements and could establish deductibles to control program expenses. Copayment amounts (limited to $10 per prescription) could vary to promote the purchase of generic drugs and could be based on a sliding income scale.

Manufacturers would be required to pay the Secretary 7% of gross sales receipts as a condition of approval for new drugs. This requirement would apply in cases where the drug manufacturer submits with the application the results of research carried out by the National Institutes of Health, or under an agreement under the Stevenson-Wydler Technology Innovation Act of 1980. The Secretary could waive this requirement if he or she determined that to do so was in the public interest.

Tax Provisions

Taxpayer Refund and Relief Act of 1999 [H.R. 2488 (Archer et. al.)]

This tax bill, *vetoed by the President* September 23, 1999, included provisions related to the deduction of medical expenses; these provisions were described as a placeholder for subsequent congressional action.

Current tax law limits deductions for medical expenses to those that exceed 7.5% of adjusted gross income. H.R. 2488 would have specified that this income threshold would not apply to prescription drug insurance coverage for Medicare beneficiaries if certain reforms were enacted. Specifically, the threshold would not apply when the following conditions were met:

- Low-income federal assistance is available to enable persons with incomes below 100% of poverty to purchase a drug-only Medigap policy or coverage through integrated comprehensive plans. Federal assistance would be phased-out for persons with incomes between 135% and 150% of poverty.
- At least one authorized Medigap policy is a drug-only policy.
- Coverage for outpatient prescription drugs for beneficiaries is provided only through integrated comprehensive health plans which offer current Medicare covered services and maximum limitations on out-of-pocket spending. Plans offered by HCFA would have to compete on the same basis as private plans.
- The tax code allows deductions for a drug, which is not currently a prescribed drug, but which was a prescribed drug in the year purchased or during the 2 preceding years.